Meeting Notes
Clinical Advisory Panel
December 11, 2001 – Department of Managed Health Care, Sacramento

Panel Members Present – Antonio Linares, M.D.; Herbert A. Berkoff, M.D.; John Alksne, M.D.

Introductions –Antonio Linares, M.D., Medical Advisor to the Director, opened the meeting of the Clinical Advisory Panel.

Consumer and Provider Survey on IMR: Mike Schults, Center for Health Service Research in Primary Care, U.C. Davis Medical Center, outlined a proposal that the Center is developing in conjunction with DMHC that will assess overall physician knowledge of IMR, together with providing an educational resource for providers.

The components of the web-based survey would include physician demographic information, a self-assessment of knowledge, questions about the basic features of the independent medical review system, feedback and recommended resource materials

The demographic variables would provide information on the physician's type of practice, length of practice, locations and experience with IMR. A simple self-assessment of knowledge would be recorded and immediate feedback provided, with links to a reading list. Additional links and information could be added as more information becomes available, including CME credit. Overall, the proposal will be constructed to provide an anonymous survey of the primary and specialty physician populations, using the demographic information to target particular groups of physicians for specific outreach efforts.

CAP member comments:

- Dr. Alksne noted that an additional query could ask whether payment responsibilities of the medical group would impact on the physicians' willingness or interest in referring and assisting patients in utilizing IMR.
- Dr. Berkoff noted that it's difficult to get physicians to look at anything and participate in such functions and sometimes hard to find things on the web.

Dr. Linares added that the HMO Help Center was also conducting direct outreach plans and that this project will be a supplement to that and other efforts to expand the awareness of both enrollees and providers about the IMR system. The interactivity of the website can be enhanced to include links that are pertinent to provider needs and concerns. Dr. Linares noted the survey will be posted after case-specific information concerning IMR results are available on the Department's website – together, these new informational features will hopefully attract interested providers to the IMR section of the DMHC site.

Other comments:

- Bobbie Reagan, Assistant Deputy Director, HMO Help Center, discussed the outreach program. It is focusing on making access as easy as possible with presentations to nursing associations, provider groups and teachers to get the word out. Dr. Berkoff noted that each hospital has a quality group that might provide a more useful resource and contact than physicians.

- Beth Cappel, Health Access, noted concerns about the program as described since it would be a self-selected subgroup of physicians and not scientifically valid. She stated she was troubled by the commingling of assessing knowledge and educational effort while supporting the accurate education of physicians. She also noted that the costs related to capitation impacts on utilization, a significant consumer protection issue.

- Jill Silverman, The Institute of Medical Quality, indicated that IMQ is completing a study on the effectiveness of IMR from 1999-2000. The results of interviews of physicians were dumbfounding – even the providers who assisted patients had no recollection or knowledge about IMR and some even denied that any of their patients had used the IMR system. IMQ concurs that there is a desperate need for education and recommends the website should downplay assessing knowledge and concentrate resources into educational efforts. She noted the reality is getting the information to the physician when needed since there is a lack of retention amidst other demands and needs. Dr. Linares concurred, noting the significance of "teachable moments."

IMR Program Analysis by Condition or Disputed Service – Dr. Wade Aubry, U.C.S.F., Institute for Health Policy Studies provided a review of the types of diagnoses and treatments presented in the IMR cases during first ten months of 2001.

- Of a total of 123 experimental/investigational reviews, 45 cases related to musculoskeletal system (back pain, arthritis, etc.), 42 were treatments relating to cancers. The next largest categories were off-label drug therapy (9 reviews) and uterine artery embolization for fibroid tumors (8 cases).
- Plan decisions to deny the experimental/investigational therapy were upheld in 78% of the reviews and overturned in 20% (24 cases). (Two cases were reversed by the health plan.) Although the plan decisions were usually upheld, three of the six stem cell therapy cases for cancer treatment were overturned; three of the nine reviews requesting medications for musculoskeletal conditions were overturned.
- Dr. Aubry noted there were 350 medical necessity reviews referred to IMR between January and October 2001. The cases can be categorized as 87 involving requests for prescription drugs, 38 concerning reconstructive surgery, 37 involving other surgical requests; 32 for specialty referrals, 24 for MRI or other imaging studies and 22 for gastric bypass for morbid obesity.
- 51% of the medical necessity reviews were upheld, 38% overturned and 11% were withdrawn by the plan, the patient or DMHC. The larger number of cases

withdrawn for medical necessity reviews was noted by Dr. Aubry as a factor that the Department could assess.

Dr. Aubry noted that there is some overlap in the cases – some treatments for apparently the same diagnosis appear in both experimental/investigational reviews and in medical necessity reviews. The number of cases is probably too small to note that the data provides any specific trends but the analysis will continue to incorporate the rest of the year's cases.

Dr. Alksne noted that it appears that in the breakout of specialty referrals, there was greater number of medical necessity overturns than upholds. He noted that if specialists in the review panel rather than primary care providers make all the decisions, this could insert a bias. He suggested more information be obtained to assess whether specialty reviewers can adequately assess primary care practice.

Aggregating IMR Results by Plans and by a Specific Disputed Treatment, Gastric Bypass -Tom Gilevich, DMHC counsel, provided an outline of the first 10 months of IMRs under the Department's system, noting a number of issues that could result in considerable further analysis and review by the Department, the plans and the Clinical Advisory Panel.

Aggregate results from IMR

- Overall Results from California's IMR system in 2001. Fifteen full-service plans have had cases go to IMR with an overall population of 19.2 million non-Medicare + Choice enrollees. There have been 123 reviews under Section 1370.4 (Investigational/Experimental) and 351 reviews for denials based on medical necessity.

- Overall utilization of IMR has been low during the first year. Based on information assembled by reports from the Kaiser Family Foundation and the American Association of Health Plans, states with IMR criteria similar to California's average about .7 reviews per 10,000 enrollees. (The range is between .2 to 1.7 per 10,000.) It appears that the total for 2001 will be about 570 cases, which is about 0.3 reviews per 10,000.

- Experimental and Investigational Reviews should be comparable to the prior IMR system in effect during 2000. The only change has been the underlying application process and the administrative system. But it's expected there will be a total of about 150 reviews based on experimental/investigational denials in 2001, less than the CY 2000 total of 188. There is an overturn rate of < 20% for 2001 compared to about 40% during 2000.

- New York published its results with comparable eligibility criteria for medical necessity reviews. During that states' first year (fiscal year 2000), they had 612

medical necessity reviews for 7.2 million HMO enrollees & insureds. For medical necessity reviews we would expect to have about 420 reviews for 2001.

We have an overturn rate of about 40% for the medical necessity cases that have gone to review.

IMR reports. The Department has two statutory requirements for assessing and reporting information from the independent medical review system. An annual audit is required under section 1374.34(e) for the combined purposes of education and enforcement and a report to the Legislature under section 1374.36 to include assessments to recoup the costs to DMHC of the IMR system and the resources and staffing required.

Questions raised from the aggregate results to date:

- How to account for the wide disparity in utilization between plans? With combined enrollments of 9.5 million, Kaiser & Blue Cross have had 79 reviews; HealthNet, Blue Shield, PacifiCare, Aetna and CIGNA with combined enrollments of 8.5 million have had 365.

- What accounts for the differences in experimental/investigational IMRs? The previous IMR system didn't require an application or even the concurrence of the enrollee. A soon-to-be-published study by The Institute for Medical Quality is expected to report that less than half of the reviews under Friedman-Knowles can be tracked to a request from the enrollee or representative. Under the system in effect in 2001, the Department makes the determination based on specific eligibility criteria and the enrollee makes the decision to proceed, not the plans.

- Medi-Cal managed care and IMR – are the cases going to Fair Hearing instead of IMR?

IMRs for Morbid Obesity. An example of where IMR findings have been trended involve whether gastric bypass surgery is medically necessary for morbid obesity. There have been 23 reviews for gastric bypass with a 100% overturn rate in the 20 cases where the dispute concerned the standard surgical procedure. The overturn rate and the determinations indicate that plan policies that may not reflect the existing medical treatment guidelines, led to identifying this as an area where the IMR results lead to an assessment of plan policies for such cases.

- The 23 cases involved 7 different plans and the reviews for gastric bypass written by 4 different reviewers. Medications were at issue in 7 other reviews (Xenical/Meridia) – 6 of them were overturned.

- The references cited by reviewers (NIH Consensus Development Gastrointestinal Surgery for Severe Obesity, Conference March 1991; Nat'l Heart & Lung Inst./NIH Clinical Guidelines, 1998) appear well-established and evidence-based. The guidelines describe two critical considerations in assessing whether surgical

intervention is appropriate - the patient's Body Mass Index ≥ 40 or ≥35 with co-morbidities and the failure of less-invasive efforts.

- The overturned gastric bypass reviews suggest that 16 of the plan denials were based on either the absence of participation in a supervised weight-loss programs for 6 or 12 months; that the morbid obesity had not been present for ≥ 5 years; or a plan policy required two weight-related co-morbidities. Reviewers have concluded that these should not have been interposed as obstacles for the medical necessity of the treatment. Overall, plan policies may be applying a rote step-by-step authorization process, without a comprehensive patient assessment of the medical needs of the individual patient.

- The reviews also indicate room for improvement in how the reviewers set out what appear to be the critical factors for determining the medical necessity for surgical intervention. Three cases fail to note BMI and five have no reference to whether the patient had been diagnosed with any co-morbidities.

- The results have also demonstrated the difficulty in comparing results from state to state. The Department has encouraged reviewers to make a decision, even if the findings are conditional. CHDR has indicated that in some state systems, those plan decisions would be upheld. In the cases involving gastric bypass procedures for example, the patients have not undergone pre-surgical psychological and lifestyle screening steps since the plan denials have occurred before that evaluation would be performed.

Dr. Alksne noted that it would be difficult to determine whether the low rates of IMR means that plans and providers are doing a good job or a bad job.

Comments.

- Mattie Hanley: Supported the Panel's further consideration of the issues as IMR experience accumulates.
- Beth Cappel: The Department should use the information to change the larger behavior of plans and to educate providers on patterns. The reasons for the IMR decisions and their consistency with the statute are important. Although there is some overlap, the two types of reviews – experimental/investigational denials and those based on medical necessity – are quite different. The consumer groups would like to work with DMHC to ensure consistency with the statute. Ms. Cappel expressed concern bias could be introduced if the reviewers confuse the different medical and scientific standards applicable to the two types of reviews. Overall, given the range of alternative treatments available the reviews should accurately reflect the range of circumstances about where science and technology are going.
- Dr. Berkoff: Need to have IMR looked at from the perspectives of different groups and organizations, as well as how it impacts the medical groups' costs. Can't have reviewers lock in to a particular type of surgery; overall, must ensure consistency down the line.

- Katrina Peltow (PacifiCare): Noted that the availability of some services remains a problem after external review. In a Medicare overturn, the plan couldn't find a provider willing to perform it due to the inherent risks of the procedure.

HMO Help Center IMR Report: **Alan Smith, IMR Project Manager, HMO Help Center** provided an overview and update of the status of IMR.

- Summaries of IMR cases are set to be posted on DMHC website in January.
- Currently 5 consumer service representatives and one supervisor work in the IMR section with daily and weekly monitoring of the status of cases
- The Help Center is tracking the IMR applications and requests that are not qualified. Among the primary reasons for the ineligible cases are:
    - the dispute involved reimbursement for service already provided
    - applicants were no longer enrolled in the plan
    - the Department lacked jurisdiction
    - no grievance had been filed
    - the dispute involved dental or other coverage issues
    - the applicant had not responded to requests for additional information.
- Since May 2001, the Department was receiving about 150-200 applications each month
- There have been few problems with how plans are complying with the IMR system. There have been two plans that have failed to provide necessary medical records requiring intervention by the Help Center but overall, plans have cooperated.

Comments:

- Jill Silverman, IMQ, noted that half of the applicants have apparently already received the services and seeking reimbursement.
- Hattie Manley supported the overall review of the system by the panel adding that the legislature devised the utilization review requirements to make sure it was a medical and not a legal review.
- Beth Cappel, Health Access, advised the Panel that the issue of retrospective reviews has been raised in the regulatory hearing; it was her understanding that they would be encompassed within the statute. The number of ineligible cases raises concern that medical necessity issues were being disguised as coverage disputes. An example would be a patient who paid for a prescription out of pocket when the pharmacy advised that the plan wasn't paying.

Dr. Alksne suggested a legal analysis of the statute to discern whether the criteria are being correctly applied.

Informational items:

- **Child & Adolescent Mental Health Stakeholders Conference.** Dr. Linares summarized the proceedings and results from the November 2, 2001 conference, noting that there was a broad support by the public and private stakeholders

involved in mental health services and on the planning committee supporting DMHC facilitating additional meetings. The meeting brought home the wide differences in the availability and coordination of services in different communities and between the public and private sectors.

- **Information on Pending IMR Studies and Reports.** Dr. Linares summarized a RAND/MAXIMUS study proposal for the U.S. Department of Labor to assess the demographic breakdowns of enrollees using California's IMR system. He also noted that additional research that may be supported by the Agency for Healthcare Research and Quality (AHRQ). AHRQ is an evidence based practice center to consider patient safety and promotion of evidence-based medicine. Dr. Linares noted that DMHC is coordinating with DHS in its survey of the policies of Medi-Cal managed care plans relating to obesity; guidelines concerning chlamydia screening and quality improvement plans. Dr. Linares also advised the Panel that Pacific Business Group of Health (PBGH) is interested in working jointly on effective management of diabetes efforts.